

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



F24

(43) International Publication Date
25 January 2001 (25.01.2001)

PCT

(10) International Publication Number
WO 01/06433 A1

(51) International Patent Classification⁷: G06F 17/60 (71) Applicant (for all designated States except US): NATIONAL DATA CORPORATION [US/US]; One National Data Plaza, Corporate Square, Atlanta, GA 30329-2010 (US).

(21) International Application Number: PCT/US00/19309 (72) Inventors; and

(22) International Filing Date: 17 July 2000 (17.07.2000) (73) Inventors/Applicants (for US only): HIRSHMAN, Alan, J. [US/US]; 9348 East Aster Drive, Scottsdale, AZ 85260 (US). WEINTRAUB, Michael, D. [US/US]; 9614 East Corrine Drive, Scottsdale, AZ 85260 (US). WALDRON, Christina, B. [US/US]; 13418 S. 38th Street, Phoenix, AZ 85044 (US).

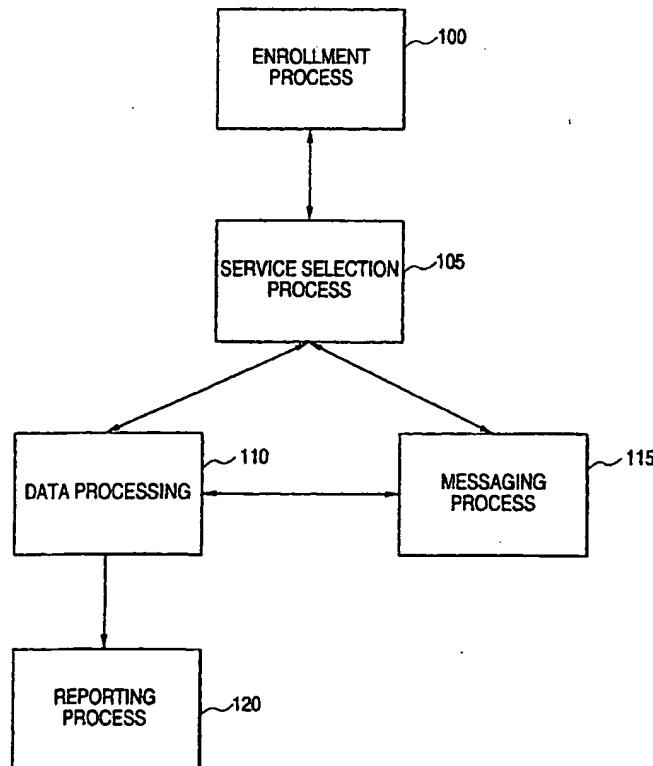
(25) Filing Language: English (74) Agents: KIMMS, Lyle et al.; Foley & Lardner, Suite 500, 3000 K Street, NW, Washington, DC 20007-5109 (US).

(26) Publication Language: English (75) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR,

(30) Priority Data: 60/143,950 15 July 1999 (15.07.1999) US (63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application: US 60/143,950 (CIP) Filed on 15 July 1999 (15.07.1999)

[Continued on next page]

(54) Title: METHOD AND SYSTEM FOR PRESCRIPTION DRUG COMPLIANCE



(57) Abstract: A computer implemented method and apparatus and system for providing and analyzing information relating to prescription drug compliance includes receiving enrollment (100) information of participating prescription users including storing user selections (105) of prescription related services and message delivery options and processing the prescription related services and message delivery options selected by the prescription users. Messages (105) are generated and transmitted based on the prescription related services and the message delivery options selected by the prescription users and participating pharmacies are notified of any required services related to the prescription related services selected by the prescription users. Information from the pharmacies relating to prescription activities of the prescription users are received and used to generate reports relating to user compliance based on the information received from the pharmacies.

WO 01/06433 A1

HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— *With international search report.*

(84) **Designated States (regional):** ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

METHOD AND SYSTEM FOR PRESCRIPTION DRUG COMPLIANCE

5 This application claims the benefit of priority under 35 U.S.C. § 119(e) of provisional application 60/143,950 entitled "Prescription Drug Compliance Method and System," filed on July 15, 1999, the disclosure of which is incorporated herein in its entirety.

BACKGROUND

Non-adherence to prescribed drug therapy is a significant health care 10 problem in the United States, leading to excessive morbidity, mortality, medical costs, and lost drug sales to retail pharmacies and drug manufacturers. According to the National Council for Patient Information and Education (NCPIE), the five most common forms of non-compliance are 1) not taking prescriptions as filled; 2) taking an incorrect dose; 3) taking the medication at the wrong time; 4) forgetting to take 15 one or more doses; and 5) stopping the medication too soon. The following statistics highlight the rates of non-compliance among prescription users:

- Over 50% of all prescriptions are taken inaccurately;
- For outpatients, 90% make mistakes taking their prescriptions;
- 21% of health care consumers never get their prescriptions refilled;
- 20 • Of those individuals that take prescriptive drugs, 1/3 take all the medication prescribed, 1/3 take some of the recommended dose, and 1/3 do not take any.

The impact of this extremely significant healthcare problem on the patient's well being and healthcare costs is enormous. Medical conditions and drug type may 25 influence rates of non-compliance. This may be due to the difficulty of maintaining the therapeutic regimen or conditions concomitant to the specific disease state. These conditions may burden the patient with challenges in refilling medications or taking them as prescribed. Studies show that the non-compliance rates are as follows for these medical conditions and drug types:

| Medical Condition | Percent of Prescription Non-Compliance |
|-------------------|--|
| Diabetes | 40-50% |
| Epilepsy | 30-40% |
| Hypertension | 40% |
| Asthma | 20% |
| Organ transplant | 18% |

| Drug Types | Percent of Prescription Non-Compliance |
|-----------------------|--|
| Antiarrhythmics | 76% |
| Chemotherapy | 73% |
| Antibiotics | 67% |
| Antiasthmatics | 54% |
| Antihypertensives | 47% |
| Lipid lowering agents | 43% |
| Anticonvulsants | 24% |
| Immunosuppressants | 18% |
| Oral contraception | 8% |

Many prescriptions today require an extended regimen for optimal health

5 benefits, thus increasing the likelihood of compliance problems. There is a significant amount of research that validates the high cost of medication non-compliance. For the patient, taking medications inaccurately has resulted in:

10

- An annual loss of life estimated to be 125,000 individuals.
- 10% of hospital admissions (estimated to cost \$15.2 billion for these 3.5 million patients).
- Over ½ of those persons hospitalized for drug reactions are over age 65.
- 23% of nursing home admissions (estimated to cost \$31.3 billion for these 380,000 patients).

15

- For society, the costs are equally astronomical:
 - Each year, \$1.5 billion in workdays are lost.
 - In 1992, the estimated costs of non-compliance to the healthcare industry were \$45 billion.

- Total annual costs of non-compliance are \$100 billion.

Causes of prescription non-compliance can be as varied as the disease states for which they are consumed. Research indicates, however, that compliance programs can have a positive impact on this costly and deadly behavior. In a study 5 of 900 patients taking antibiotics, a physician group practice found those patients receiving a reminder postcard or follow-up phone call were less likely to need a second course of antibiotic therapy because improved compliance resulted in better health outcomes.

Prescription compliance also results in business benefit to the pharmacy. 10 Repeat visits will increase the likelihood of ancillary purchases. Promotional campaigns sent to consenting consumers allow the pharmacy to target product promotions to appropriate individuals. Also, the pharmacy wants the patient to refill at the same pharmacy as opposed to a competitor.

Moreover, it is difficult to non-intrusively collect information regarding the 15 prescription activity and co-relate the prescription activity to the different features and options of a prescription drug compliance system. Thus, gathering accurate data, to further improve the prescription drug compliance program based on customized data, such as the demographics of the patients and the geographical locations of the pharmacies and the patients, has been difficult in the past.

Accordingly, there is a strong need for a way of making patients properly 20 take prescription drugs. In addition, there is a strong need to analyze the results of such compliance programs when the patients are provided timely, customized reminders using state of the art technology in a prescription drug compliance system as the patients conduct their prescription activities at one or more pharmacies. The 25 present invention addresses these needs.

SUMMARY OF THE INVENTION

The present invention relates to a method and a system that can ensure 30 effective prescription compliance. The system can be particularly effective for pharmacies, physicians, hospitals, health insurance, etc. The present invention can include a process and system for enrolling participating prescription users for any or

all prescription compliance services via their choice of any or all automated delivery mechanisms. Information regarding the patient, the number of refills, the prescription refill date, and prescription instructions can be stored in a data warehouse or other suitable data store. Personalized push technology can generate

5 message content based on the prescription instructions, date of fill, and the number of refills required. The reporting processes can use service subscription data and prescription activity data to generate reports on the impact on prescription compliance of personalized messaging.

The prescription drug compliance method can include a system that enables

10 enrolling participating prescription users and allows enrolled or enrolling users to select one or more prescription compliance services, which can include a reminder to fill a prescription and a reminder to take a prescription. Information regarding the patient, the number of refills, the prescription refill date, prescription instructions, and compliance services selected by the user can be stored in one or

15 more databases.

Information from the databases can be processed, based on the prescription instructions, date of fill, and the number of refills required to generate messages based on the compliance service selected. The enrolled users can be notified about

20 prescription drug compliance based on the services selected. Any participating pharmacy or pharmacies can be notified as to the services required from them.

Information, including such as whether the user responded to the prescription compliance notification, can be collected from the selected pharmacy or pharmacies. Reports on the impact on prescription compliance can be generated, based on the service subscription data and prescription activity, including feedback

25 (i.e., information collected or received or transmitted from the pharmacies) received from the participating pharmacies.

The present invention encompasses a computer implemented method of providing and analyzing information relating to prescription drug compliance that includes: receiving enrollment information of participating prescription users,

30 including storing user selections of prescription related services and message delivery options; processing the prescription related services and message delivery

options selected by the users; generating and transmitting messages based on the prescription related services and the message delivery options selected by the users; notifying participating pharmacies of any required services related to the prescription related services selected by the users; receiving information from the 5 pharmacies relating to prescription activities of the users; and generating reports relating to user compliance based on the information received from the pharmacies.

Other aspects of the present invention include the software and the system to implement the method described above. In this regard, the present invention also encompasses a computer readable medium having program code recorded thereon 10 for providing and analyzing information relating to prescription drug compliance. The program code can comprise first through sixth program codes for processing user enrolled information and generating reports. The first program code can enroll participating prescription users, including storing user selections of prescription related services and message delivery options. The second program code can 15 process the user selections of prescription related services and message delivery options. The third program code can generate and transmit messages based on the prescription user selections of the prescription related services and the message delivery options. The fourth program code can notify participating pharmacies of any required services related to the prescription related services selected by the 20 prescription users. The fifth program code can receive information from the pharmacies relating to prescription activity of the prescription users. The sixth program code can generate user compliance reports related to prescriptions based on the information received from the pharmacies.

The present invention also encompasses a system for providing and 25 analyzing information relating to prescription drug compliance. The system can include enrollment, data processing, messaging, communication, and report generation sections. The enrollment section can enroll participating prescription users, including storing user selections of prescription related services and message delivery options. The data processing section can process the prescription user 30 selections of prescription related services and message delivery options. The messaging section can generate and transmit messages based on the prescription

user selections of the prescription related services and the message delivery options. The communication section can notify participating pharmacies of any required services related to the prescription related services selected by the prescription users and receives information from the pharmacies relating to prescription activity of the 5 prescription users. The report generation section can generate user compliance reports related to prescriptions based on the information received from the pharmacies.

The user compliance reports can include reports correlated to demographics of the prescription users, the prescription related services to the prescription 10 activities of the prescription users, the message delivery options to the prescription activities of the prescription users.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features, aspects, and advantages of the present invention will become more apparent from the following description and accompanying 15 drawings, which are briefly described below.

FIG. 1 shows an overall process flow diagram of the present drug compliance system.

FIG. 2 shows a process flow diagram of various enrollment options for the prescription compliance services.

20 FIG. 3 shows compliance service and accompanying delivery method options for patients.

FIG. 4 shows a block diagram of the three data processing options to load prescription activity into the operational data storage.

25 FIG. 5 shows a process flow diagram of prescription compliance message delivery.

FIG. 6 shows a block diagram of data flow for generating specific report types.

FIG. 7 shows the enrollment process flow diagram of the interaction between the pharmacist, customer, and the pharmacy management system.

30 FIG. 8 shows a process flow diagram detailing the paper enrollment process.

FIG. 9 shows a process flow diagram detailing the web enrollment process.

FIG. 10 shows a process flow diagram of an overview of the technical systems that can be used to carry out the present invention.

FIG. 11 shows a diagram of the hardware components that support a 5 database system that can be used to carry out the present invention.

DETAILED DESCRIPTION

As an alternative to traditional “opt out” or passive prescription compliance services, the present invention can provide a “patient-care driven” system that allows the patient the autonomy to “opt-in” for participation, by selecting 10 prescription related service types, and message delivery options that promote prescription compliance.

A preferred embodiment of the present invention, as shown in FIG. 1, includes an enrollment process 100 for enrolling patients into the prescription compliance and analysis/reporting system of the present invention. A service 15 selection process 105 can allow the patient to select the different combination of prescription related services and message delivery options. A data processing component 110 can process the patient data (including the patient's selections) and other related data from the pharmacies and from its own data store. A messaging process 115 can communicate messages to the patients and the pharmacies based on 20 the patients' selections and the pharmacies' requirements. A reporting/analysis process 120 can analyze and report prescription compliance correlated to at least patient information, pharmacy information, disease or medicine information, prescription related service information, and message delivery information.

Referring to FIGS. 1 and 2, a new patient enrollment process 100 for the 25 prescription compliance services and receipt of promotions can occur in at least one of four ways: 1) pharmacy management system (“PMS”), 2) paper enrollment, 3) network access using a terminal at a pharmacy, physician's office, or insurance provider, or 4) network access using a computer or other information processing device belonging to a patient.

It is to be understood that the term "customer," "patient," and "prescription user" are used interchangeably, and herein means in any person or service that obtains prescription drugs from a supplier, such as a pharmacy (in the tradition sense), hospital, physician's office, virtual store that sells prescription drugs through

5 the Internet, or other services, such as wholesalers, distributors, and manufacturer, that can supply prescription drugs. Other people (non-patient) or service providers can perform prescription activity on behalf of some patients or even another service provider. These other people or service providers are also included within the meaning of "patient" in the present disclosure. For example, disabled or elderly

10 patients may rely on other people or service providers to conduct their prescription related activity including pick-up, ordering refills, and ensuring their timely consumption.

As shown in FIG. 2, the pharmacist can initiate the PMS method during his interaction at the pharmacy counter with a pharmacy customer. It is to be

15 understood that the "pharmacy" broadly encompasses any store, service, or location where the patient can order or pickup prescription drugs in the present disclosure. The "pharmacist" as used in the present disclosure also means, in addition to the pharmacist in the traditional sense, any person educated in the benefits of prescription compliance and the features of the "opt-in" compliance program.

20 In step 205, the pharmacist can interact with the patients, and asks the patient, for example, if he or she would like to participate in this compliance program. In steps 206 and 207, the pharmacist can explain the program and answer any of the patient's questions relating to the compliance program. If the patient agrees to participate, a record of informed consent is obtained in step 208.

25 Depending on the pharmacy's preference in the preferred embodiment, in step 209-212, consent to enter the program can be obtained, for instance, by paper enrollment log signature, electronic signature stored in the PMS database, or verbal consent, which can be logged in the PMS database. In the embodiment illustrated, the pharmacy management system can be a software program, such as DATASTAT,

30 that is loaded onto the pharmacy's computer network. On the patient's demographic profile screen, there can be a software selection for entering that the

patient has consented to participate in the compliance program. Additional screens can allow the pharmacist to enter the patient's prescription related service choices and messaging delivery (or device) choices. The pharmacist can enter this information into the PMS as it is received from the patient, for instance, at the

5 pharmacy counter or physician's office. At the end of the business day, this patient information file can be sent to the subscription database 250 via electronic batch data extract process initiated using, for example, a subscription API 213 provided by the prescription compliance system. Alternatively, the subscription database 250 can be updated in an online mode.

10 FIG. 7 illustrates in detail, an example of the process of interaction between the pharmacist, customer, and the pharmacy management system. The process requires the pharmacist to drive the consumer's enrollment via data entry through the software's prompts. In step 701, the patient can fill the prescription at the pharmacy. In steps 702-704, the system can prompt the pharmacist to ask the

15 patient whether he or she would like to join the compliance program. If in step 705, the patient declines to join, the pharmacy management system and its database can be updated in step 706 and 707 (so that future refills for this medication does not again prompt the pharmacist to ask the patient to join). If the patient decides to join the compliance system in step 705, the pharmacist, prompted by the system, obtains

20 informed consent in steps 708-712. In step 713, the pharmacist can enter in the system that informed consent has been obtained.

Thereafter, the system can prompt the pharmacist for the prescription related services and their corresponding message delivery options in steps 714 and 715. As examples, steps 716-717 show the refill alert service option and the prompts for its

25 message delivery options, steps 718-719 show the daily compliance reminder service option and its message delivery options prompt, steps 720-721 show the expired prescription notification service option and its message delivery options prompt, and step 722-723 show the promotional materials service option and its message delivery service option. Thereafter, in step 724, the system can prompt for

30 each message delivery options for a selected service options, and further in step 725, patient's messaging delivery option details can be entered, including optionally

a customized message for each patient that can be entered by the patient or can be selected by a patient from a list. Finally, the system can validate the enrollment record in step 726 to complete the enrollment process through the pharmacist.

As shown in FIG. 2, in steps 216 and 217, the paper enrollment process 215 5 allows the consumers to fill out a paper enrollment form obtained at the patient's pharmacy, doctor's office, or sent to their home by their pharmacy. In step 218, the patient's signed consent, as well as their prescription profile, prescription related service selections, and messaging delivery (or device) selections, can be collected.

The completed enrollment form (also termed business response card) can be 10 mailed or sent to a data collection site in step 219 or left at the pharmacy in step 220 or can be entered by the patient using a web or other data entry interface as shown in step 221. The enrollment form left at the pharmacy can be collected and mailed to the data collection site in step 222. Alternatively, the data can be entered directly at the pharmacy via a data entry interface to the prescription compliance system 15 20 according to the present invention. At the data collection site, in step 223, the information obtained on the enrollment form can be entered into the subscription database 250 of the prescription compliance system of the present invention. The data entry can be done by a remote data entry interface that uses the subscription web application interface. The signed enrollment form can be filed (or scanned) for future reference, if desired.

FIG. 8 illustrates an example of the paper enrollment process and sequence of events that can occur when a consumer (or patient) requires modification of their profile. The patient completing the paper enrollment can initiate this component of the prescription compliance program in step 801. Upon receiving the enrollment 25 form, the data entry staff can access a secure connection to the enrollment interface, which guides entering the enrollee's profile in steps 802 and 803. This interface can also be used to modify an existing record. Therefore, in step 804, if a new record is to be entered, the enrollment data entry process is initiated by using an electronic form in step 805. The patient's information, including name, mailing address, 30 phone or contact information, date of birth, medication name, and prescription details, can be entered in step 806.

Thereafter, the system can prompt the data entry staff for the prescription related services and their corresponding message delivery options in steps 807 and 808. As examples, steps 809-810 show the refill alert service option and the prompts for its message delivery options, steps 811-812 show the daily compliance 5 reminder service option and its message delivery options prompt, steps 813-814 show the expired prescription notification service option and its message delivery options prompt, and step 815-816 show the promotional materials service option and its message delivery service option. Thereafter, in step 817, the system can prompt for each message delivery option for a selected service option and further in 10 step 818, patient's messaging delivery option details can be entered, including optionally a customized message for each patient that can be provided by the patient. Finally, the system can validate the enrollment record in step 819 to complete the paper form enrollment process.

In steps 820 and 821, a paper enrollee as well as a pharmacy management 15 system enrollee can contact a call center in step 822 to modify their profile. Of course, alternative communication methods, such as e-mail or regular mail, may also be used to communicate to a call (or change) center for profile modification. In steps 823 and 824, the call center performs the modification process by choosing a record to modify in step 824, modifying the chosen record in step 826 and 20 validating the changed record in step 827.

Returning to FIG. 2, a web site interface can provide another enrollment method into the prescription compliance system of the present invention. In this enrollment method, patients or consumers can access a personal computer (or other terminal) linked to the Internet (or other public or private network) in the pharmacy 25 store in step 225. Consumers can receive compliance program education from the pharmacist and be directed to enroll in the compliance program using the web subscription application interface provided on the pharmacy's PC. This PC could be located in a kiosk for ease access. In step 226, the patient can access a web page that provides the patient with the information necessary to give informed consent 30 and understand the benefits and features of the program. The patient then can complete the on-line enrollment process and indicate their consent via this on-line

form. If paper signature is required, a paper enrollment signature log can be optionally incorporated. The profile information entered via the web interface can be sent by a live Internet (or other network) link into the subscription database 250. In step 227, the patient is provided the ability to change or discontinue their services

5 by using a secure password.

In step 228, the consumers can enroll in the compliance program from anywhere they have access to the Internet (or other private or public network), such as their home or work. The web page would provide the patient the information necessary to give informed consent and understand the benefits and features of the

10 program. The patient can complete the on-line enrollment process and indicate their consent via this on-line form. The profile information entered can be sent via an Internet link into the subscription database 250.

FIG. 9 illustrates an example of the process of web enrollment where the consumer can enter their profile information via the user-friendly web-enabled

15 enrollment form. This process also allows the consumer to return later to modify any component of their profile or to elect to no longer receive the compliance program services. In steps 901-903, the patient can access the web site interface to enroll in the program, or in steps 920-922, the patient can access the website interface to modify an existing record. If in step 904, a new record is to be entered,

20 the enrollment process is initiated via an electronic form in step 905. The patient information, including name, mailing address, phone or contact information, date of birth, medication name, and prescription details, etc., can be entered in step 906.

Thereafter, the system can prompt the patient for the prescription related services and their corresponding message delivery options in steps 907 and 908. As

25 examples, steps 909-910 show the refill alert service option and the prompts for its message delivery options, steps 911-912 show the daily compliance reminder service option and its message delivery options prompt, steps 913-914 show the expired prescription notification service option and its message delivery options prompt, and steps 915-916 show the promotional materials service option and its

30 message delivery service option. Thereafter, in step 917, the system can prompt for each message delivery options for a selected service options and further in step 918,

patient's messaging delivery option details can be entered, including optionally a customized message for each patient that can be provided by the patient. Finally, the system can validate the enrollment record in step 919 to complete the web interface based enrollment process.

5 The patient can modify an existing record in step 923 by choosing a record to modify in step 924, modifying the chosen record in step 925 and validating the changed record in step 926.

Regardless of which method the patient chooses to enroll, the patient's subscription profile resides in the subscription database 250. Creating and 10 programming such a database system is well within the abilities of one skilled in the art. The subscription database server hardware can include, for example, tape drive, memory, processors having relational database servers, file systems, telecommunications hardware, keyboard, mouse, and monitor. FIG. 10 represents an overview of the major technical software and hardware components that can 15 drive the prescription compliance program.

As shown in FIG. 10, a messaging software and hardware component 1001, a service hardware and software component 1002, a subscription (or enrollment) interface hardware and software 1003 and a data load (and update) component 1004 can interact with a prescription activity operational data store hardware/software 20 component 1007 by using communication technology links 1006. These system components collaborate to generate a dynamic recipient list 1008 based on the service selections and other date/time related trigger events. The dynamic recipient list 1008 can be used to execute and deliver messages in step 1009 by using the appropriate messaging devices in step 1010.

25 FIG. 11 provides a pictorial representation of exemplary system hardware components that can be used to support the systems of the present invention. A relational database server 1101 (a computer system with database server software loaded thereon) can be connected to input/output devices 1102-1104 and telecommunications hardware 1105 that can connect it to data storage means, which 30 can include file systems 1106, tape drives 1107, and memory 1108. Furthermore, one skilled in the art would recognize that the system components and hardware

disclosed herein is exemplary only and many other such configurations could be used to implement the system and method of the present invention.

Once the patient has "opted-in" to the program and provided their consent, he or she is given the opportunity to choose any or all of the exemplary prescription

5 related services listed below:

1. Refill Reminder will send a personalized message to the patient a specified number of days before the prescription is due for a refill.
2. Refill Alert will send a personalized message to the patient when a refill is due or a specified number of days after the prescription should have been refilled.
- 10 3. Daily Compliance Reminder will send a personalized message to the patient at the time the prescription should be administered detailing the product name, dosage, and time of administration.
4. Expired Prescription Notification will send the patient and the prescribing physician personalized notification that there are no more refills available for the
- 15 5. The patient may also elect to receive promotional materials from the pharmacy that may include coupons, product information, and disease management information.

Referring to FIG. 3, for each service, the patient may choose from a host of messaging devices (or message delivery options). Not all devices are available for each service. The devices can be, for example, phone, fax, letter, pager, email, PDA, wireless device, and web page on a desktop or laptop browser application or a WAP or other application on a wireless device. Specifically, FIG. 3 shows a detailed process flow diagram outlining service options and message delivery. 20 devices. The user will receive their choices via the methods discussed above detailed in FIG. 2. These choices can be presented by one of three means: the pharmacist in spoken communication, a paper enrollment packet form, or the web subscription application interface. The user will indicate which service(s) they would like to receive from the compliance program and whether they would like to 25 receive promotional materials. They will also choose which messaging devices 30

they want utilized. The consumer can choose as many services and messaging devices as they would like. Their preferences can be indicated, for instance, by:

1. By voice during the course of dialogue with the pharmacist if using enrollment via the Pharmacy Management System.
- 5 2. By a checkmark or circled choice if using the paper enrollment form.
3. By point-and-click or other interactive technology if using the web interface.

The patient's choices can be stored in the subscription database 250. Using a toll free number or the Internet (or other network interface), the patient can be provided with the option of changing services or messaging devices or

10 discontinuing services at their discretion.

For example, as shown in FIG. 3, if a patient chooses to receive a refill reminder in steps 301-302, the message delivery choices 303 can include e-mail, fax, voice-mail, pager alert, computer generated letter or communications from the pharmacy. If the patient chooses a refill alert in steps 304-305, the message 15 delivery choices 306 can include e-mail, fax, voice-mail, pager alert, and computer generated letter or pharmacy generated communications. If the patient chooses to receive a daily compliance reminder in steps 307-308, the message delivery options 309 can include e-mail, fax, voice-mail and pager alert. If the patient chooses to receive expired prescription notification in steps 310-311, the message delivery 20 options 312 can include e-mail, fax, voice-mail, pager, computer generated letter, or pharmacy originated communications. If the patient chooses to receive promotional materials in steps 313-314, the message delivery options 315 can include e-mail, fax, and regular mail.

Referring to FIG. 4, in a preferred embodiment, the prescription activity data 25 can arrive in the operational data store 400 via any of the following three ways:

1. The pharmacy 401 can choose to send the patient's prescription activity data via a daily electronic batch data extract process using an optional temporary data store 402. This would be performed using dedicated router line existing between the pharmacy 401 and the prescription activity operational data store 30 (ODS) 400.

2. Another option for data transfer is an online daily (or other frequency) batch processing connection routed from the pharmacy management system through a main data switch (mainframe systems and hardware) 403. Prescription activity is sent to the ODS 400 from the switch 403 via a dedicated router line.
- 5 3. The third option for data transfer has the pharmacy 401 send data weekly (or at other frequency) via a secure tape media that is processed weekly (or at other frequency) into the ODS 400. Operations staff will take the tape and put into the tape machine and then initiate a batch process designed to load, transform, and populate the ODS 400. The ODS 400 itself can use the following hardware:
10 relational database server, memory, file systems, telecommunications hardware, keyboard, mouse, and system console.

Referring to FIG. 5, the automated messaging process can use personalization push technology, exceptional conditions, and recurring schedules as triggers to kickoff personalized, electronic messages. The automated messaging
15 software and system requires hardware, which can reside in the relational database server and can have the following components: tape drive, memory, file systems, telecommunications hardware, keyboard, mouse, and monitor.

The present invention's personalization engine allows developers to create patient care services that automatically customize the information for each patient
20 recipient. With dynamic recipient lists (DRLs) and message templates, the software can automatically customize the message, delivering to each patient only the information that is relevant to his prescribed daily drug regimen. This approach can be also used to notify the patient when their prescription is due for a refill or when a specific promotion meets their needs. The scheduled and trigger driven services can
25 send personalized information to patient subscribers at pre-defined intervals or when other metrics exceed pre-defined threshold conditions ensuring appropriate information is delivered only when it is required.

As shown in FIG. 5, the messaging software 501 can access both the subscription database 250 and the prescription activity ODS 400 schedule and
30 trigger events and services in step 501. As shown in steps 502-513, the messaging software can generate dynamic recipient lists and personalized message content for

each prescription related service so that the messages can be created and delivered in step 514 using one or more of the message delivery options shown as 515.

As shown in FIG. 6, one aspect of the present invention is that the subscription database 250 and the prescription activity operational data store 400 5 can be accessed to analyze and generate reports relating to various aspects of the patient's prescription compliance.

Therefore, actual prescription activity (across a multitude of pharmacies) can be measured against prescription related services received and messaging devices (or delivery options) used to compare product success rates. The reporting features 10 can use a unique identifier key (e.g., social security number) linking the subscription records stored in the subscription database 250 to the prescription activity data stored in the ODS 400. Once the records are linked, statistical reports and analyses can be run to determine the impact of the compliance program on 15 prescription activity. The suggested hardware can include a personal computer that can access the data stores using SAS software for analyses.

As shown in FIG. 6, the aggregate data from both the subscription database 250 and the prescription activity data store 400, sorted by a unique identifier for each patient, are available in data store 601. These data can then be used for analysis and reporting of compliance effectiveness correlated to any of the stored or 20 derived data fields. Some examples of such reports include service option and message delivery reports that are correlated to subscriber demographics 603 and/or utilization of service types and messaging options 604. Compliance reports 605 can include one or more of correlation between service type and prescription activity 606, correlation between message delivery options and prescription activity 607 and 25 a persistency ratio determination 608 defined as the ratio of the number of days supplies are consumed divided by the number of the dispensing days available for the supplies. Prescription activity reports 609 can include reports based on one or more of patient and prescription counts including product/class comparisons by store (or pharmacy) 610, correlation between demographics and prescription 30 activity 611, and multiple regressions performed to determine predictive value of demographics, time, receipt of service, and messaging delivery options on

prescription activity 612. Reports related to date of prescription refills 613 can include reports related to correlation of time to refill for service recipients and non-recipients by selected time period, patient demographics, store (or pharmacy) location, and product or therapeutic class 614 and reports related to number of refills and number of refills by product and class 615.

Given the disclosure of the present invention, one versed in the art would appreciate that there may be other embodiments and modifications within the scope and spirit of the present invention as defined by the following claims. Accordingly, all modifications attainable by one versed in the art from the present disclosure 10 within the scope and spirit of the present invention are to be included as further embodiments of the present invention.

What is claimed is:

1. A computer implemented method of providing and analyzing information relating to prescription drug compliance, comprising:
 - receiving enrollment information of participating prescription users, including storing user selections of prescription related services and message delivery options;
 - processing the prescription related services and message delivery options selected by the prescription users;
 - generating and transmitting messages based on the prescription related services and the message delivery options selected by the prescription users;
 - notifying participating pharmacies of any required services related to the prescription related services selected by the prescription users;
 - receiving information from the pharmacies relating to prescription activities of the prescription users; and
 - generating reports relating to user compliance based on the information received from the pharmacies.
2. The method according to claim 1, wherein receiving enrollment information of prescription users includes one of a pharmacist entering user selections of prescription related services and message delivery options, entering data received from the prescription users, electronically receiving data entered by the prescription users at a kiosk or a terminal, or receiving electronic data directly entered by the prescription user using an interface on a personal communications device.
3. The method according to claim 1, wherein the prescription related services include a refill reminder, a refill alert, a daily compliance reminder, an expired prescription notification, and receiving promotional materials.
4. The method according to claim 1, wherein the message delivery options include electronic mail, facsimile, computer generated voice mail, pager alert, computer generated letter, and alert to a wireless communication device.

5. The method according to claim 1, wherein receiving information from the pharmacies includes one of a periodic batch update, an online update, and a secure data transfer using a physical transfer of a data storage medium.
6. The method according to claim 1, wherein generating reports relating to user compliance includes correlating the prescription related services to the message delivery options selected by the prescription users.
7. The method according to claim 6, wherein generating reports includes correlating the reports to demographics of the prescription users.
8. The method according to claim 1, wherein generating reports includes correlating the prescription related services to the prescription activities of the prescription users.
9. The method according to claim 1, wherein generating reports includes correlating the selected message delivery options to the prescription activities of the prescription users.
10. The method according to claim 1, wherein generating reports includes determining a persistency ratio of the users defined as a ratio of a number of days the prescriptions are consumed by the prescription users to a number of available dispensing days for the prescriptions.
11. The method according to claim 1, wherein generating reports includes prescription activity reports correlating prescription activities to the pharmacies.
12. The method according to claim 1, wherein generating reports includes correlating the prescription activities and demographics of the prescription users.

13. The method according to claim 1, wherein generating reports includes using multiple regression analysis to predict effects of demographics, time, prescription related services, and message delivery options on prescription activities.
14. The method according to claim 1, wherein generating reports includes correlating a time to refill for participating prescription users to selected time periods, user demographics, pharmacy locations, or product or therapeutic class of prescriptions.
15. The method according to claim 1, wherein generating reports includes correlating a number of refills and a number of doses per refill with product or therapeutic class of prescriptions.
16. A computer readable medium having program code recorded thereon for providing and analyzing information relating to prescription drug compliance, the program code comprising:
 - a first program code that enrolls participating prescription users including storing user selections of prescription related services and message delivery options;
 - a second program code that processes the user selections of prescription related services and message delivery options;
 - a third program code that generates and transmits messages based on the prescription user selections of the prescription related services and the message delivery options;
 - a fourth program code that notifies participating pharmacies of any required services related to the prescription related services selected by the prescription users;
 - a fifth program code that receives information from the pharmacies relating to prescription activity of the prescription users; and
 - a sixth program code that generates user compliance reports related to prescriptions based on the information received from the pharmacies.

17. The computer readable medium having program code recorded thereon according to claim 16, wherein the user compliance reports includes reports correlated to demographics of the prescription users.

18. The computer readable medium having program code recorded thereon according to claim 16, wherein the user compliance reports includes reports correlating the prescription related services to the prescription activities of the prescription users.

19. The computer readable medium having program code recorded thereon according to claim 16, wherein the user compliance reports includes reports correlating the message delivery options to the prescription activities of the prescription users.

20. A system for providing and analyzing information relating to prescription drug compliance, comprising:

an enrollment section that enrolls participating prescription users including storing user selections of prescription related services and message delivery options;

a data processing section that processes the prescription user selections of prescription related services and message delivery options;

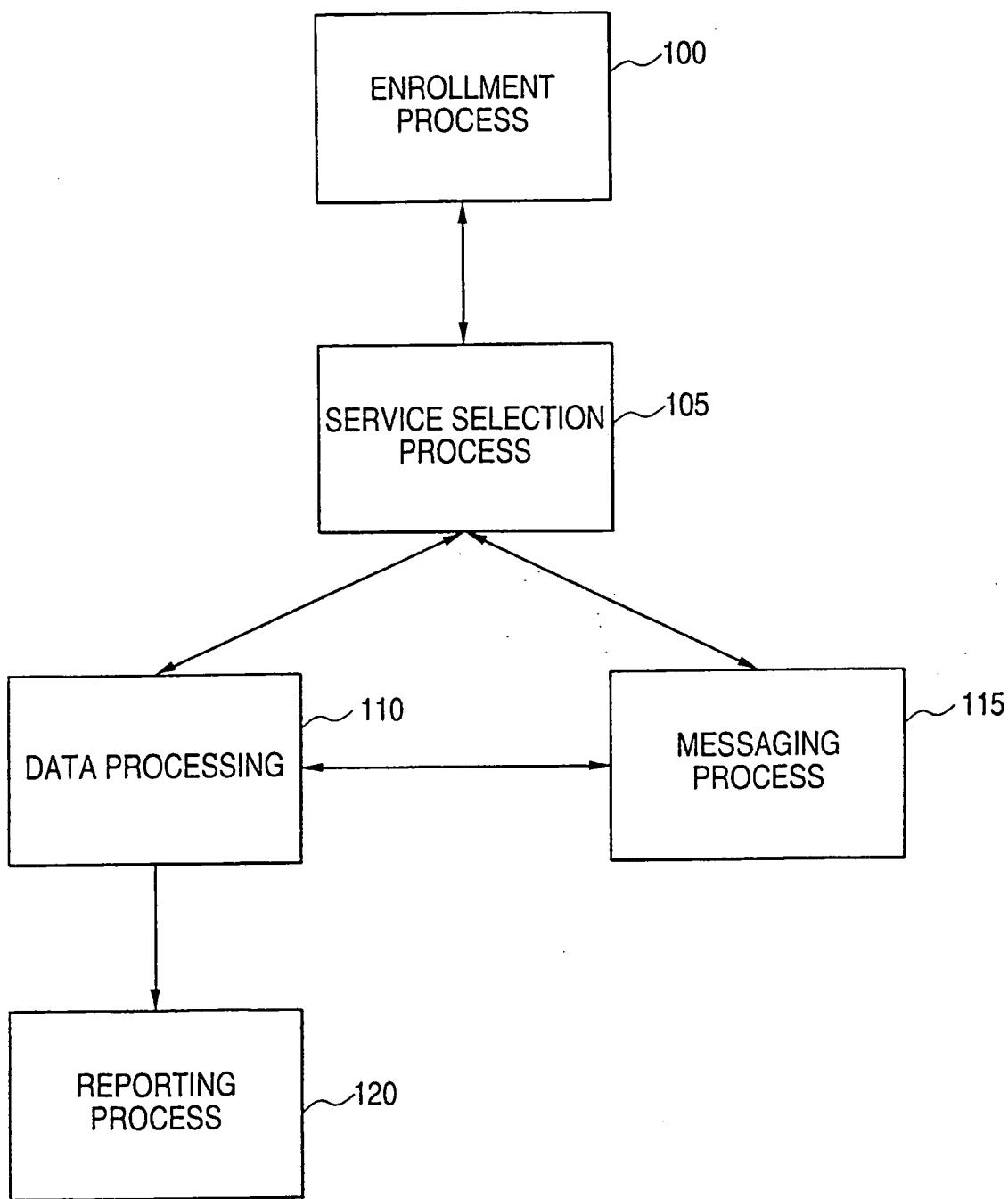
a messaging section that generates and transmits messages based on the prescription user selections of the prescription related services and the message delivery options;

a communication section that notifies participating pharmacies of any required services related to the prescription related services selected by the prescription users and receives information from the pharmacies relating to prescription activity of the prescription users; and

a report generation section that generates user compliance reports related to prescriptions based on the information received from the pharmacies.

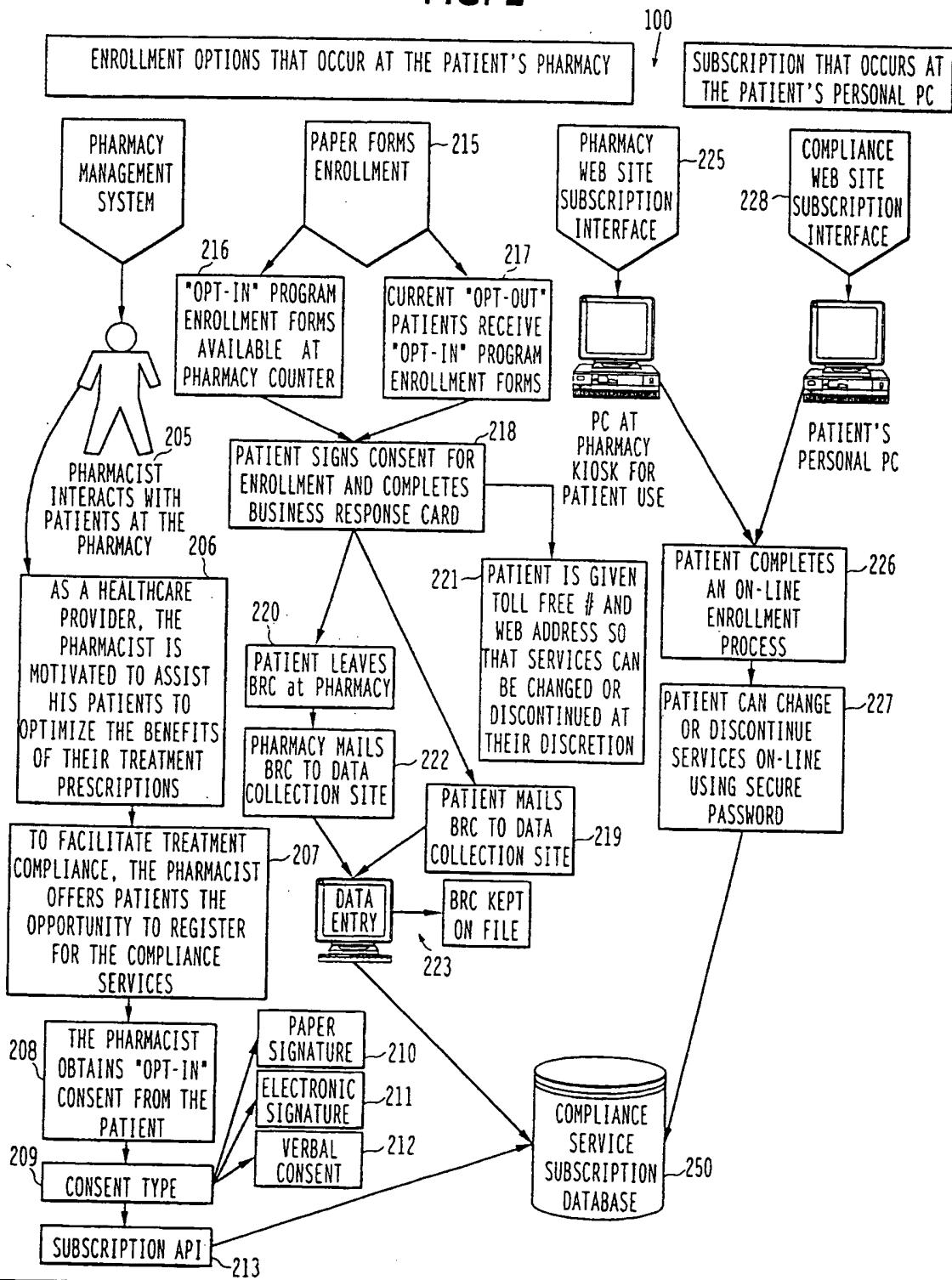
I/II

FIG. 1



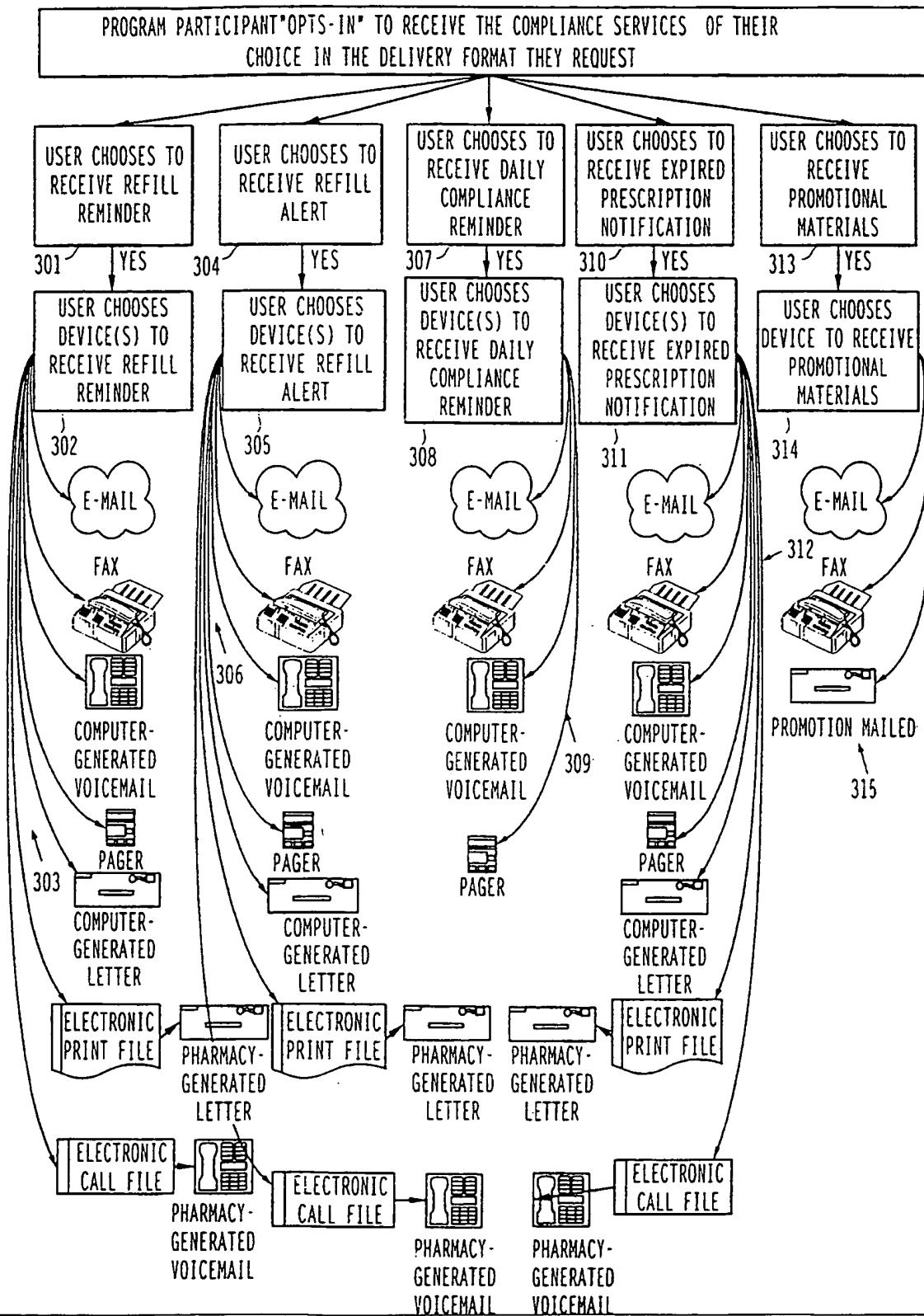
2/II

FIG. 2

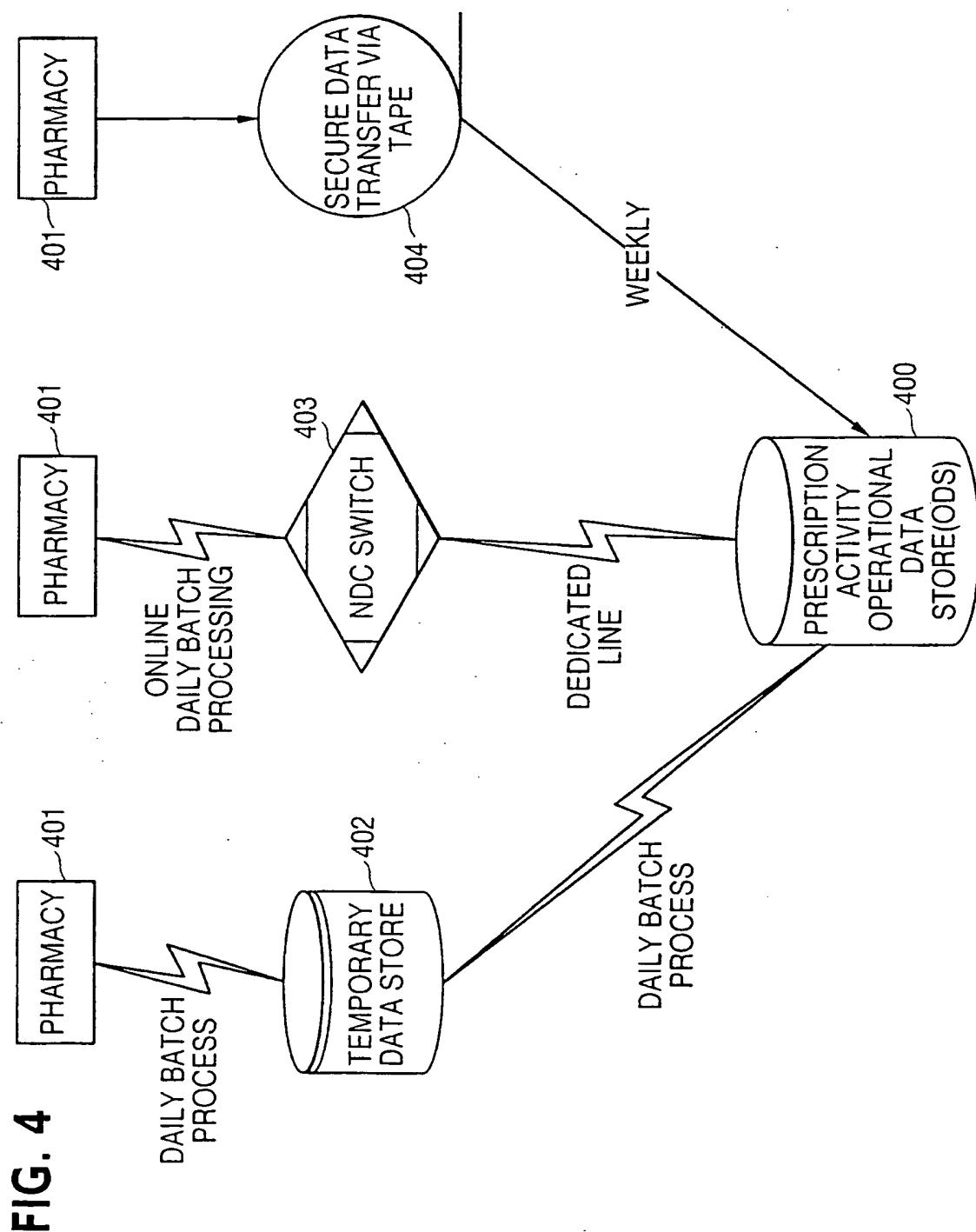


3/II

FIG. 3

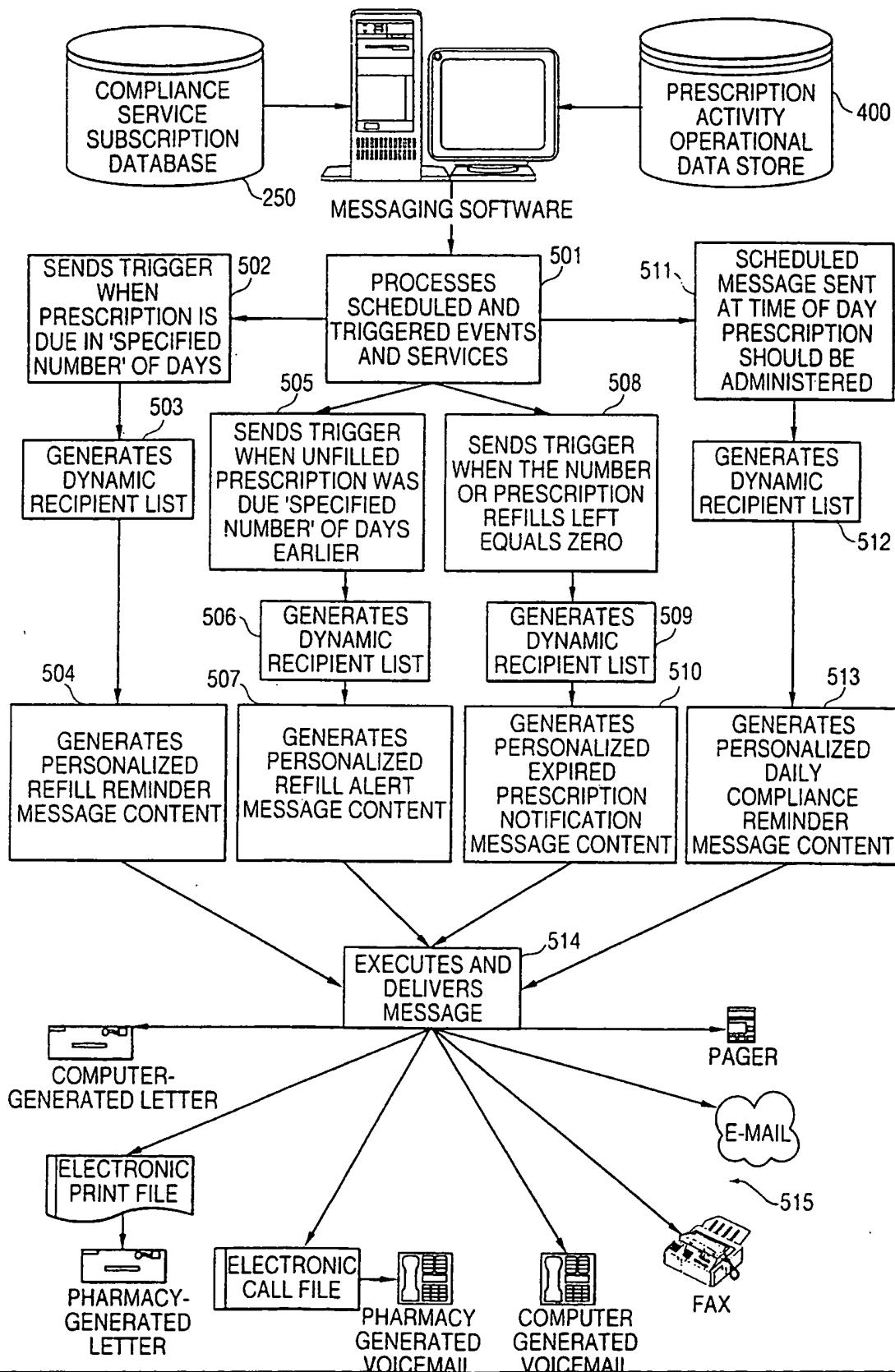


4/11



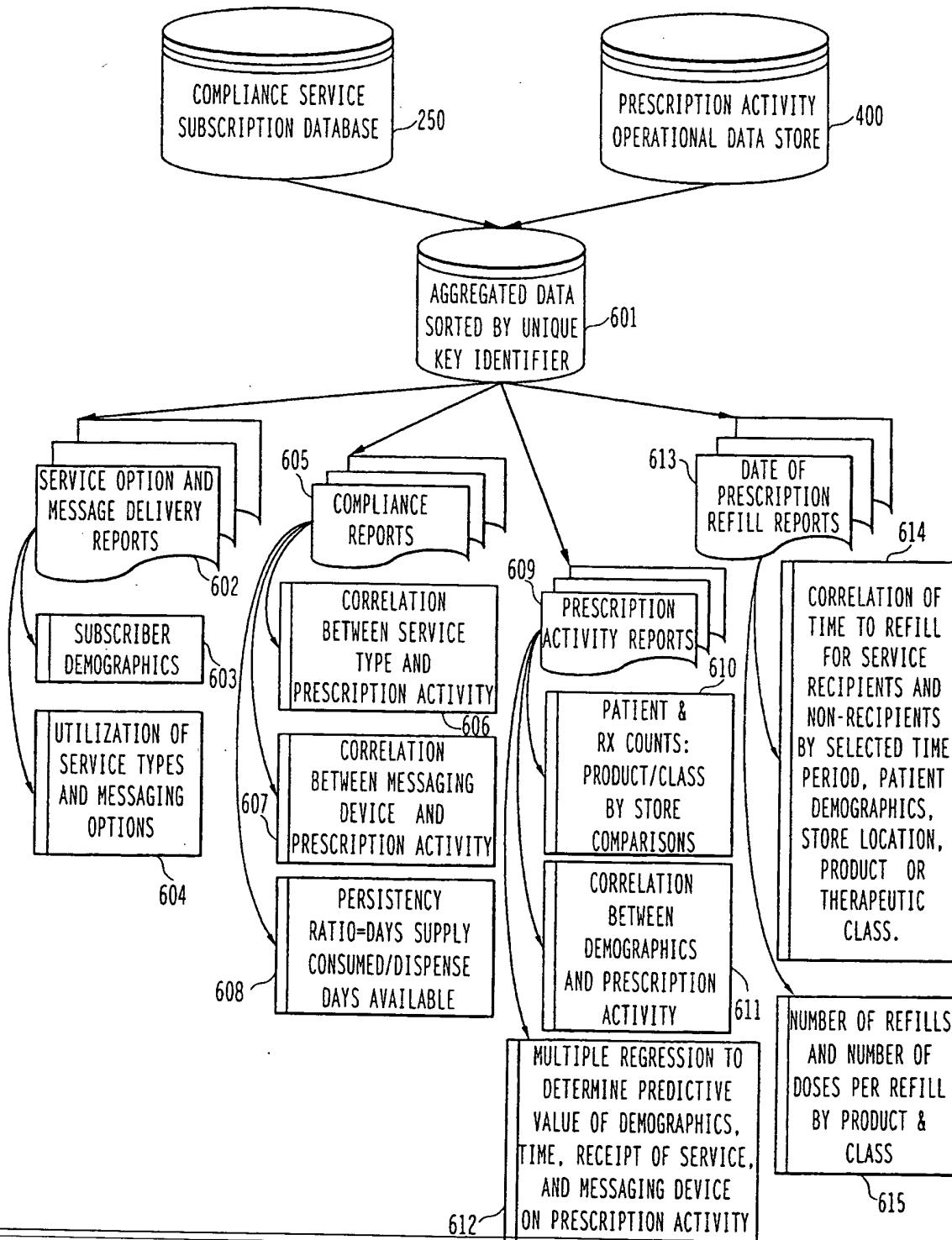
5/II

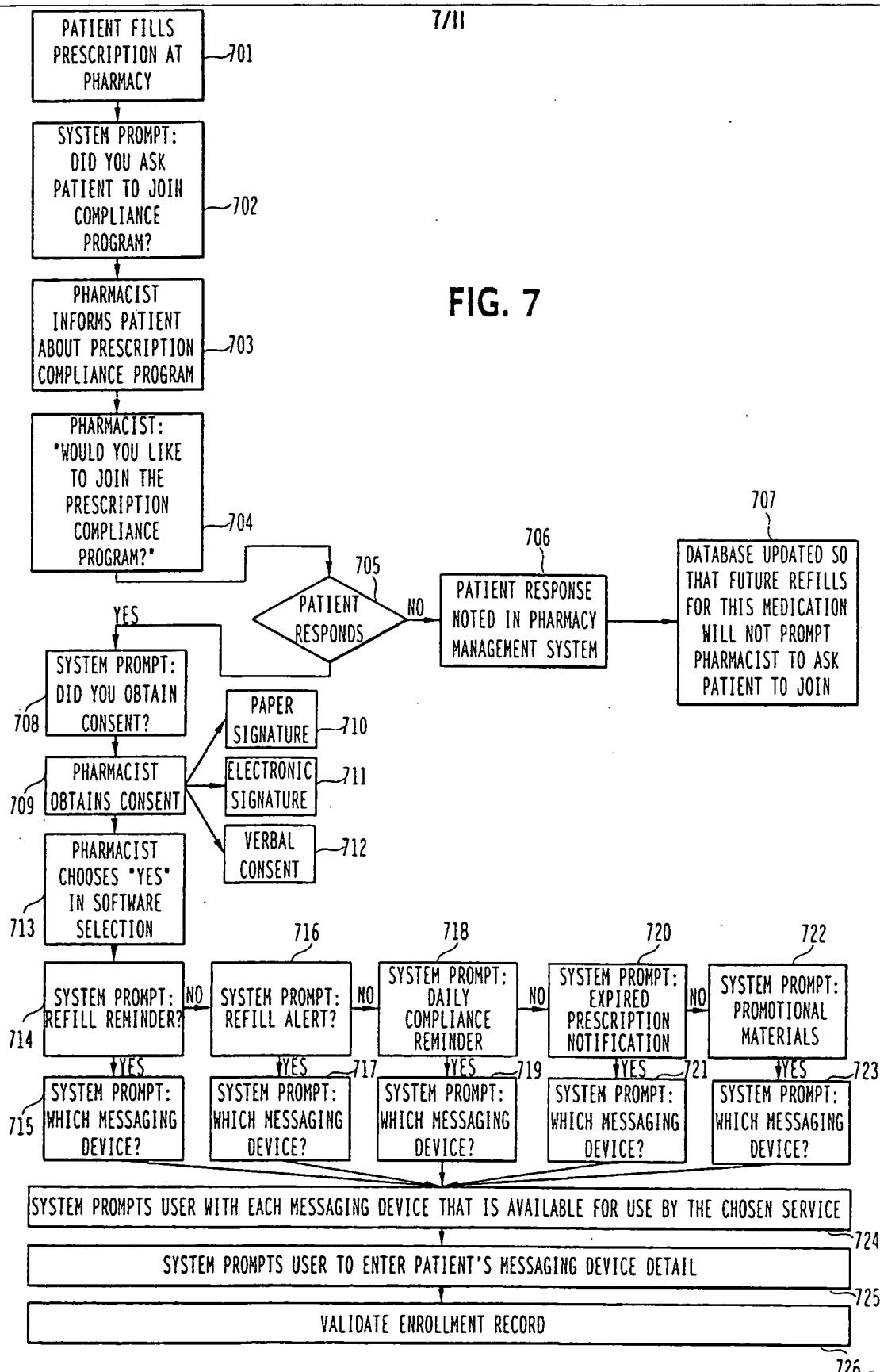
FIG. 5



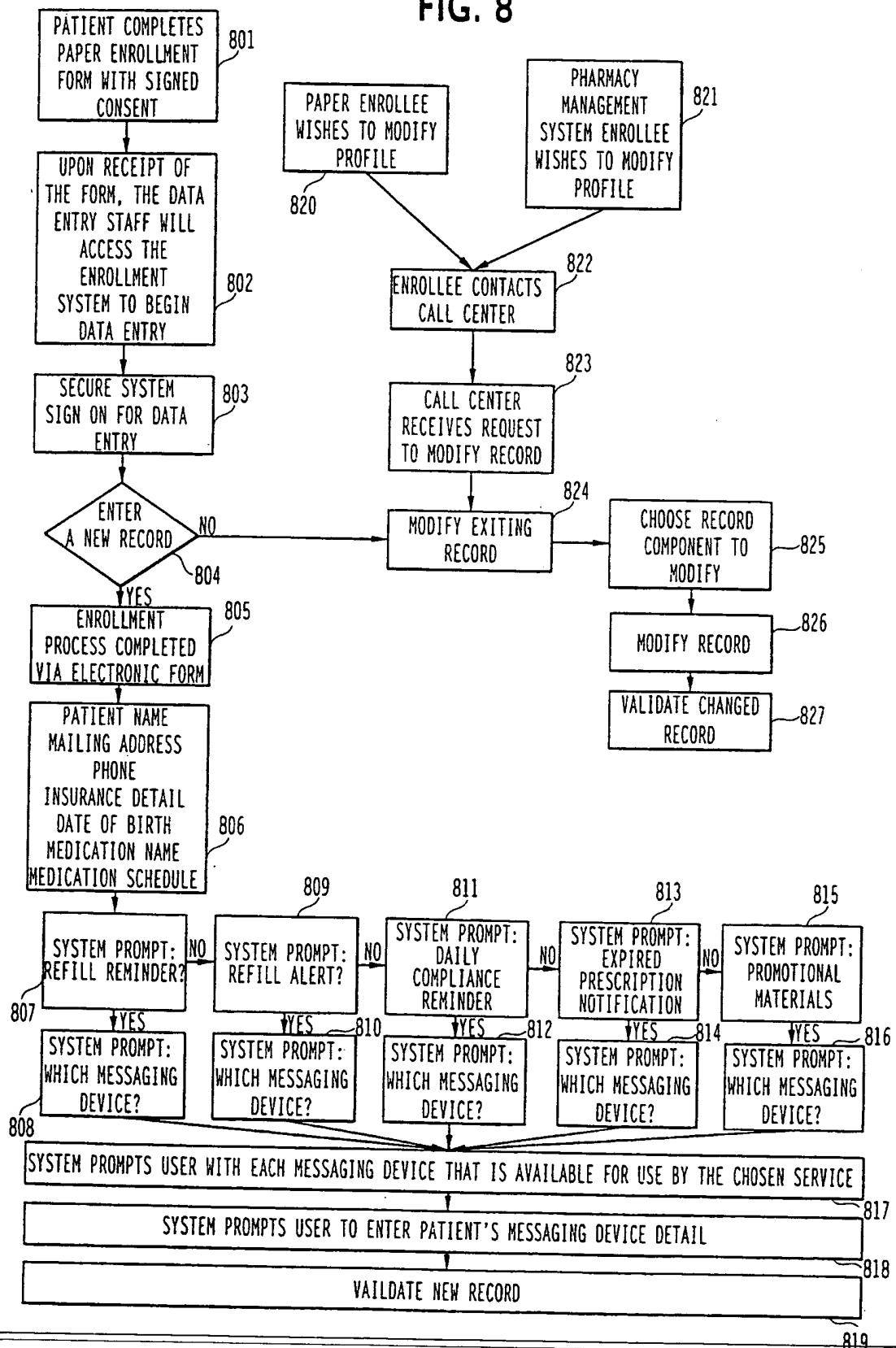
6/II

FIG. 6



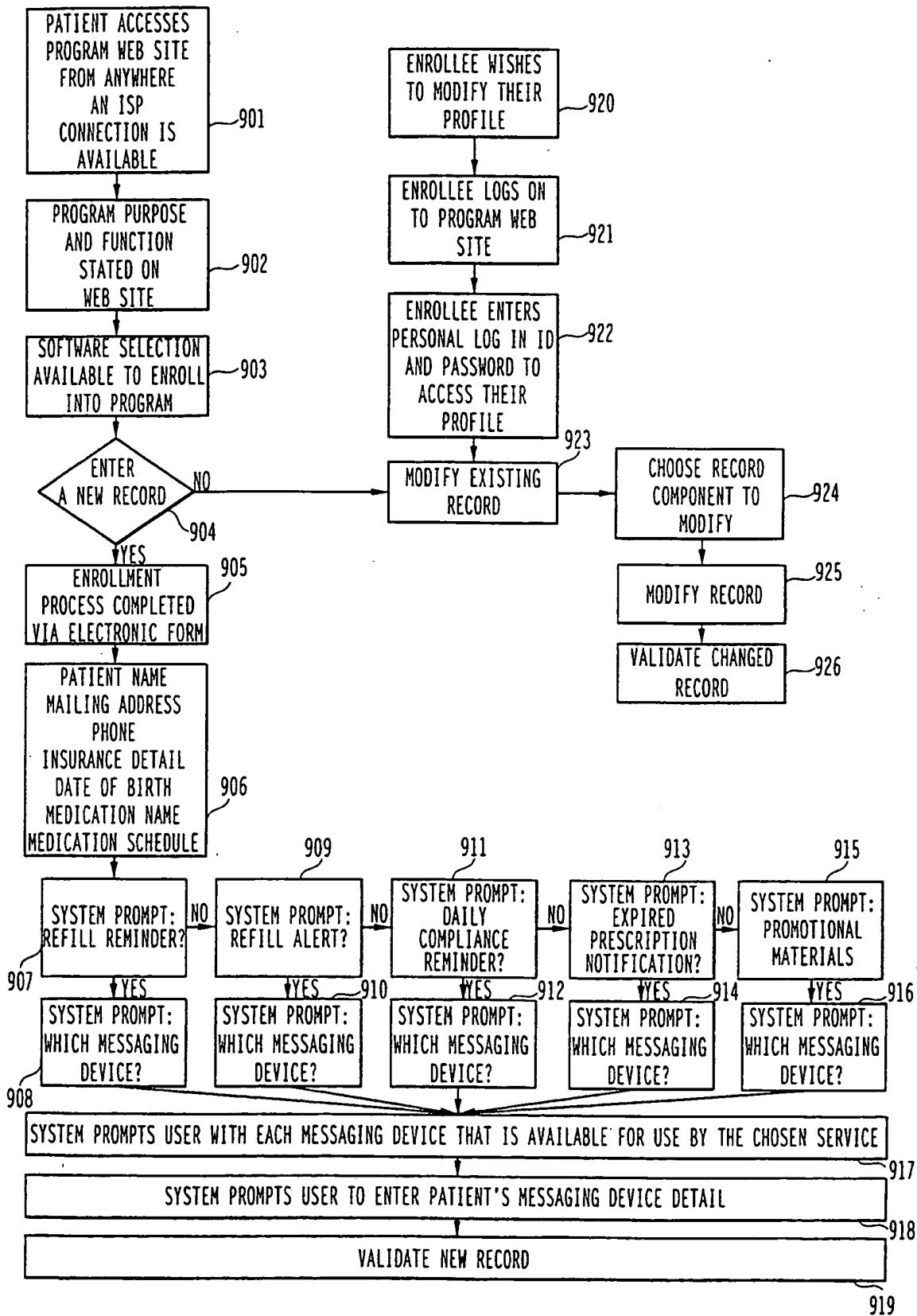


8/II
FIG. 8



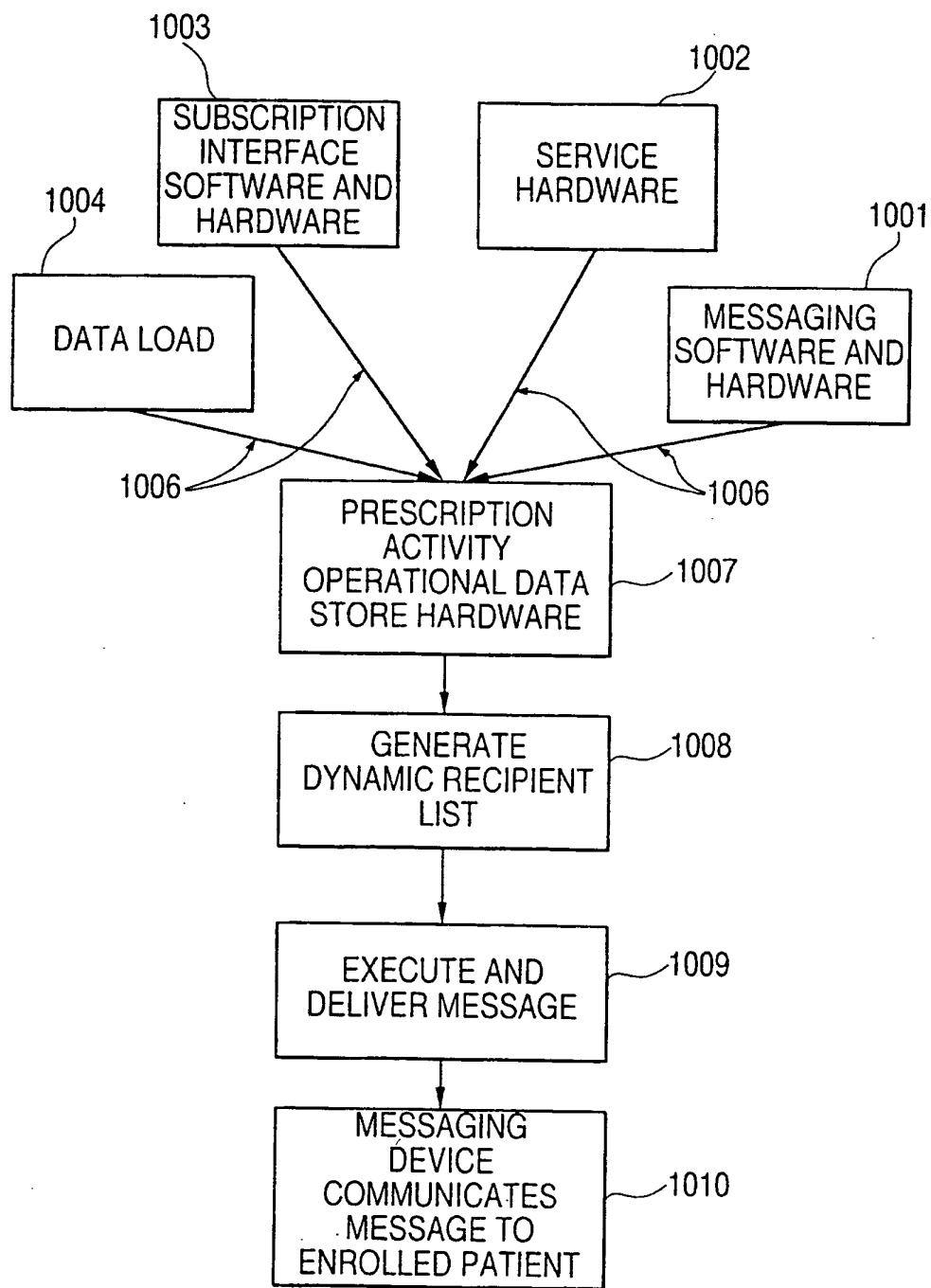
9/II

FIG. 9



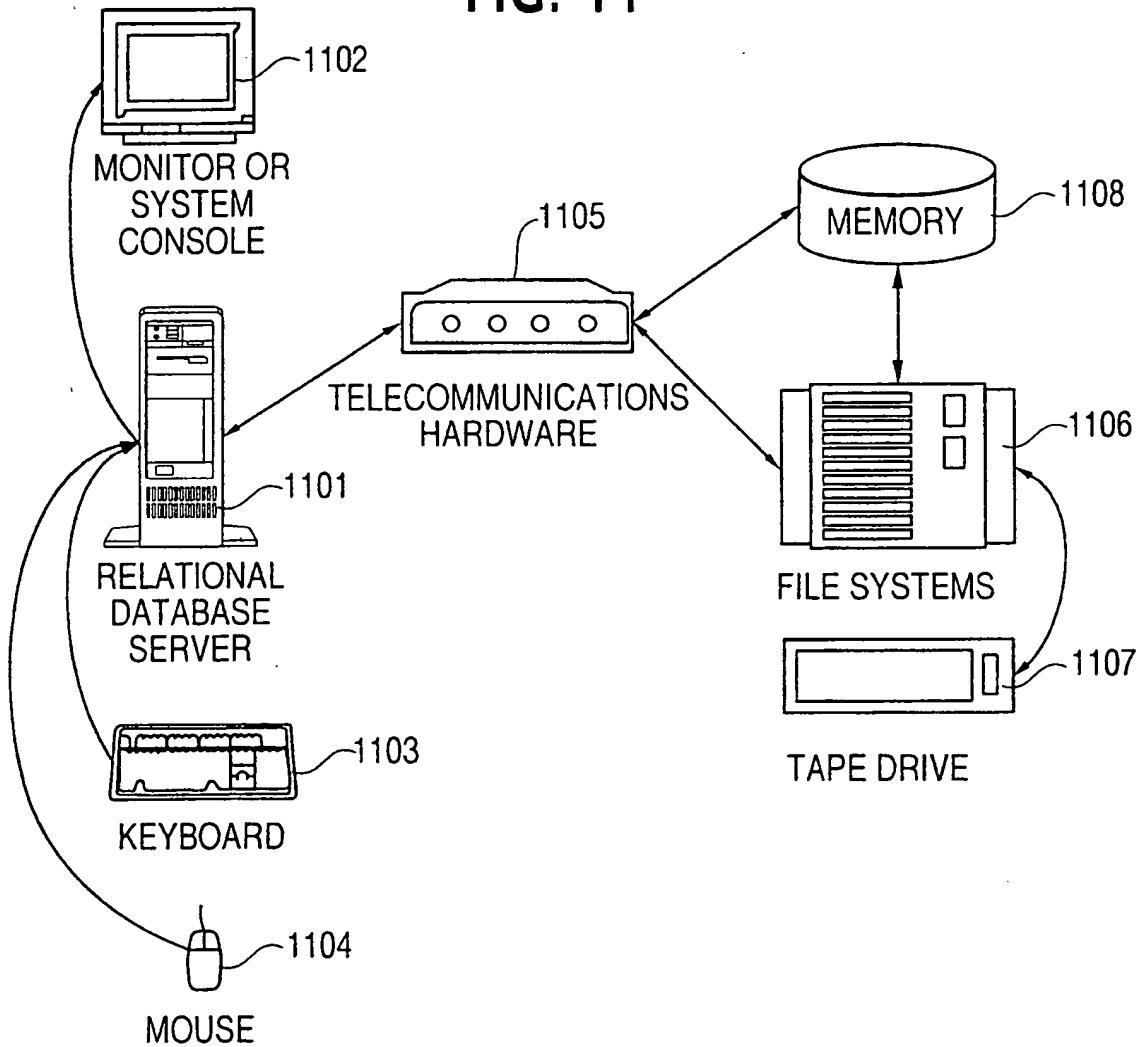
10/II

FIG. 10



II/II

FIG. 11



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/19309

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :G06F 17/60
US CL :705/2, 3

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 705/2, 3

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST 2.0, CAS ONLINE, DIALOG, IEEE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| A | US 4,766,452 A (PILARCZYK) 23 August 1988, see entire document. | 1-20 |
| A | US 5,577,335 A (TUCKER) 26 November 1996, see entire document. | 1-20 |
| A | US 5,612,869 A (LETZT et al) 18 March 1997, see entire document. | 1-20 |
| A | US 5,713,487 A (COUGHLIN) 03 February 1998, see entire document. | 1-20 |
| A | US 5,774,865 A (GLYNN) 30 June 1998, see entire document. | 1-20 |

Further documents are listed in the continuation of Box C. See patent family annex.

| | | |
|--|-----|---|
| Special categories of cited documents: | "T" | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "A" | | document defining the general state of the art which is not considered to be of particular relevance |
| "E" | "X" | earlier document published on or after the international filing date |
| "L" | | document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) |
| "O" | "Y" | document referring to an oral disclosure, use, exhibition or other means |
| "P" | "&" | document published prior to the international filing date but later than the priority date claimed |

Date of the actual completion of the international search

28 AUGUST 2000

Date of mailing of the international search report

03 OCT 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Faxsimile No. (703) 305-3230

Authorized officer

TOD SWANN

James R. Matthews

Telephone No. (703) 308-7791